LABEL IN PART: (Case) "Black Walnut Meats . . . grade large [or "grade small"] Donig Co., Inc. San Francisco, Calif."

LIBELED: 5–10–62, N. Dist. Ill.

CHARGE: 402(a)(3)—contained *E. coli;* and 402(a)(4)—prepared and packed under insanitary conditions.

DISPOSITION: 5–29–62. Consent—claimed by Donig Co., Inc., and reconditioned.

28991. Shelled mixed nuts. (F.D.C. No. 48789. S. No. 80–741 V.)

QUANTITY: 37 cases, each containing 12 cans, at San Francisco, Calif.

SHIPPED: 4–30–63, from Portland, Oreg., by Johnson Nut Co.

LABEL IN PART: (Can) "Johnson's Home Treat Mixed Nuts * * * 1 Pound Net Weight * * * Johnson Nut Company, Minneapolis, Portland."

RESULTS OF INVESTIGATION: The article was approximately 5.87 percent short weight.

LIBELED: 5–24–63, N. Dist. Calif.

CHARGE: 403(e)(2)—when shipped, the article failed to bear a label containing an accurate statement of the quantity of contents, since the label statement "1 Pound Net Weight" was inaccurate.

DISPOSITION: 7–12–63. Default—delivered to a charitable institution.

28992. Pinon (pine) nuts. (F.D.C. No. 48450. S. No. 21–442 V.)

QUANTITY: 12 80-lb. bags, at San Francisco, Calif.

SHIPPED: 10–19–62, from Gallup (Gamerco), N. Mex., by Navajo Shopping Center.

LABEL IN PART: (Tag) "Navajo Shopping Center Gamerco, New Mexico."

LIBELED: 11–15–62, N. Dist. Calif.

CHARGE: 402(a)(3)—contained animal excreta pellets when shipped.

DISPOSITION: 4–5–63. Consent—claimed by Desert Sun Co., San Francisco, Calif. Reconditioned; 35 lbs. destroyed.

VITAMIN, MINERAL, AND OTHER PRODUCTS OF SPECIAL DIETARY SIGNIFICANCE

28993. Sta-trim candy bar. (F.D.C. No. 44248. S. No. 61–900 P.)

QUANTITY: 50 ctns., each containing 24 individually wrapped ¾-oz. bars, at San Francisco, Calif.

SHIPPED: 12–1–59, from Yonkers, N.Y., by Sta-Trim Confections, Inc., Div. of American Dietaids Co., Inc.

LABEL IN PART: (Bar) "Sta-trim * * * MILK style CHOCOLATE flavored WITHOUT ALL THE FATTENING CALORIES of ordinary chocolate bars No Sugar added* A Dairy Maid product by Sta-trim Ingredients: Skim and whole milk solids, calcium carbonate, cocoa butter, mannitol, chocolate liquor, lecithin, natural and artificial flavors, .06% saccharin and .016% sodium cyclamate. Saccharin and sodium cyclamate are non-nutritive artificial sweetners which should be used only by persons who must restrict their intake of ordinary sweets. Approx. Analysis*: Protein 8%, Fat 31%, Available Carbohydrates 14%. Approx. Calories per 100 grams 3 67–Approx. Calories per bar 76. Sta-Trim Confections, Inc., Yonkers, N.Y. Dist."

RESULTS OF INVESTIGATION: Examination showed the article to be a light brown colored candy bar divided into four equal sections. The article had the odor, taste and appearance of chocolate.

LIBELED: 2–23–60, N. Dist. Calif.; amended libel 10–21–60.

CHARGE: 402(d)—when shipped, the article was a confectionery and it contained saccharin and sodium cyclamate, which are nonnutritive substances; 403(a)—the label statements "Low Calorie," "Good for you when you diet—Good for you when you want to keep trim," and "For People Who Want To Keep Trim," were false and misleading since the article was not low in calories and would not be effective to reduce weight or to keep trim; 403(a)—the label statement "WITHOUT ALL THE FATTENING CALORIES of ordinary chocolate bars" was misleading since the article furnished the consumer a substantial proportion of the fattening calories of ordinary chocolate bars; 403(a)—the label statement "ONLY 9 CALORIES per section" was misleading because the label did not declare that there were 8 small sections and the consumer could not see how many sections there were until the package was opened; 403(a)—the label statement "ONLY 9 CALORIES" in bold large print followed by the words "per section" in light small print was misleading because it created the impression that each bar furnished fewer calories than it did in fact, and this misleading impression was not corrected by the statement in the fine print portion of the label "Approx. Calories per bar 76"; and 403(g)(1)—the article failed to conform to the definition and standard of identity for milk chocolate.

DISPOSITION: On or about 3–17–60, Sta-Trim Confections, Inc., claimed the article and denied that the article was misbranded or adulterated. On 10–11–60, the claimant filed a motion for partial summary judgment in the claimant's favor on the adulteration charge of the libel. On 11–9–60, the Government moved for summary judgment in its favor. On 2–6–61, both motions for summary judgment were argued, and on 4–14–61, the court granted the defendant's motion, denied the Government's motion, and rendered the following opinion:

SWEIGERT, *District Judge:* "This is a libel filed by the United States praying seizure and condemnation in accordance with the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Sections 301 et seq., of 1200 candy bars, more or less, manufactured by Sta-Trim Confections, Inc., a New York corporation, and shipped in interstate commerce to San Francisco, California.

"The libel, as amended on October 21, 1960, alleges that these candy bars were adulterated when introduced into and while in interstate commerce within the meaning of 21 U.S.C. Section 342(d) in that they are confectionery containing non-nutritive substances. Further, that the candy bars were misbranded when introduced and while in interstate commerce within the meaning of 21 U.S.C. Section 343(a).

"Sta-Trim Confections, Inc., has intervened, claiming the articles seized, and moves for a partial summary judgment on the ground that libelant's allegations of adulteration, under 21 U.S.C. Section 342(d), are insufficient as a matter of law, and that there is no genuine issue of fact on that issue.

"Libelant has also moved for summary judgment on both charges, adulteration and misbranding.

"On the issue of adulteration, the amended libel alleges that the Sta-Trim bars are adulterated within the meaning of 21 U.S.C. Section 342(d), in that they are confectionery and contain saccharin and sodium cyclamate, which are alleged to be non-nutritive substances.

"This section reads in pertinent part as follows: 'A food shall be deemed to be adulterated . . . (d) If it is confectionery, and it bears or contains any alcohol or non-nutritive article or substance except authorized coloring, harmless flavoring . . .'

"Claimant contends that its candy bars are not confectionery, but special dietary foods within the meaning of 21 U.S.C. Section 343(j). That section reads as follows: 'A food shall be deemed to be misbranded . . . (j) If it purports to be . . . for special dietary uses, unless its label bears such information concerning its vitamin, mineral and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.'

"Webster's New International Dictionary, (2nd Ed. 1949), defines confectionery as 'sweetmeats in general; things prepared and sold by a confectioner; confections; candies.' The Court has examined samples of the seized items, which are part of the record, and is satisfied that these products conform to this definition as to odor, appearance and taste.

"Claimant's promotional literature, attached to Inspector Forbragd's affidavit, characterizes its own product as 'candy . . . that tastes like and looks like the real thing', Ex. 4; 'low calorie candy that really tastes delicious', Ex. 4; 'low calorie candies that taste like, are priced like and sell like regular chocolate,' Ex. 5. The name of the manufacturer itself is Sta-Trim Confections, Inc.

"The fact, asserted by claimant, that its products are intended for a special dietary purpose, does not necessarily exclude their classification as confectionery. The two classes of foods, confectionery and special dietary foods, are not treated by the statute as separate and distinct. While a special provision exists in the code dealing with foods for special dietary purposes, 21 U.S.C. Section 343(j), it does not appear in the statute or in the regulations promulgated thereunder that any immunity from the other provisions of the law was intended for special dietary foods.

"The regulations declare to the contrary. 21 C.F.R. 1.11(b) states: 'No provision of any regulation under Section 403(j) of the act [21 U.S.C. Section 343(j)] shall be construed as exempting any food from any other provision of the act . . .'

"With specific reference to special dietary foods containing saccharin, the regulations state, 21 C.F.R. 125.7: . . . 'The provisions of this section shall not be construed as . . . relieving any food from compliance with any requirement of Sections 402 (b) or (d), 403(g), or other provisions of the act.' [21 U.S.C. Sections 342 (b) or (d), 343(g)].

"The Court concludes that Sta-Trim Candy Bars are confectionery within the meaning of Section 342(d).

"There remains the question whether, as confectionery, this product is adulterated within the meaning of the same section in that it contains saccharin and sodium cyclamate, which are alleged to be non-nutritive substances.

"It will be noted that the statute, Section 342(d), refers to non-nutritive substances 'except authorized coloring or harmless flavoring.'

"The libel does not negate the possibility that saccharin and sodium cyclamate, although non-nutritive, are harmless flavorings. We are of the opinion that, unless such exception is negated, the libel, for that reason, fails to state a case of adulteration under the section.

"The Affidavit of Osborn, filed by the libelant, alleges that 'in industry, in government, and among consumers, and in standard reference books, sugar and sugar substitutes such as saccharin and sodium cyclamate are commonly understood to be, and are universally recognized as sweeteners or sweetening agents and not flavoring substances.'

"The Affidavit of Okin, filed by claimant, does not specifically allege that its products are either sweetening agents or flavoring agents. It does, however, state that 'saccharin and sodium cyclamate have been added to the product to sweeten it without adding the calories contained in ordinary sugar,' and the same affidavit quotes the legend prominently displayed on the label of its candy bars: 'saccharin and sodium cyclamate are non-nutritive artificial sweeteners . . .'

"Only in claimant's briefs, which do not constitute part of the record, is there an attempt to urge that the candy bars contain harmless flavorings.

"While the libel, therefore, does not negate the possibility that these substances may be harmless flavorings, and may be considered defective in this regard, libelant's affidavit, which has not been controverted by claimant's affidavit, draws the distinction between flavoring and sweetening agents, and indicates that saccharin and sodium cyclamate are sweetenings and *not*

flavorings. We assume, therefore, that the libel can be amended to allege the fact in accordance with the affidavit.

"Libelant has not, however, alleged that, even as sweetenings, these substances are harmful, and, absent any such allegation, we shall assume that they are harmless.

"The further question is therefore presented whether Section 342(d) is to be construed as prohibiting the use in confectionery of non-nutritive substances which are not harmful or inedible.

"When Congress enacted the Food and Drug Act in 1906, its obvious purpose was to eliminate from confectionery certain non-nutritive substances which were poisonous or deleterious ingredients. Section 7 of the Act, 21 U.S.C. Section 8, predecessor to Section 342(d) read as follows: 'That for purposes of this Act an article shall be deemed to be adulterated . . . In the case of confectionery: If it contains terra alba, barytes, talc, chrome yellow, or other mineral substance or poisonous color or flavor, *or other ingredient deleterious or detrimental to health*, or any vinous, malt or spiritous liquor or compound or narcotic drug.' [Italic added.]

"When Congress enacted the present law in 1938, the section was broadened to omit references of specific harmful substances and there was substituted the general phrase, 'non-nutritive substance,' with certain specific exceptions in regard to authorized coloring and harmless flavoring.

"At the Senate hearings upon the new section, the then Chief of the Food and Drug Administration, W. G. Campbell, explained: 'That particular phrase "or non-nutritive substance" was intended to take care of the candy-carrying trinkets of the sort that have been in the recent past extremely popular.' Dunn, *Federal Food, Drug and Cosmetic Act, A Statement of Its Legislative Record*, 1065 (1938).

"The Senate Committee on Commerce reported on the bill as follows, quoted in Dunn, supra, 680, 691: 'Forbids traffic in confectionery containing metallic trinkets and other inedible substances which have been found to be a menace to the welfare of children.'

"In 6 Law and Contemporary Problems, 27–28 (1939), it is said: 'The old act listed certain non-nutritive substances and alcohol, the presence of which would render the product adulterated. This list was inadequate, especially in that it failed to cover the practice of placing tiny toys and trinkets in children's candy, which may cause injury or death when swallowed.'

"It appears, therefore, that Section 342(d), when read in light of its predecessor Section 7 of the 1906 Act, embodies a legislative purpose to prohibit non-nutritive ingredients which are either harmful or inedible.

"The problem of adulteration in confectionery is different from that of other foods. Other foods may undergo certain types of treatment in processing and packing, exposing them to the risk of adulteration through the addition of foreign matter. Confectionery, on the other hand, by definition is an incorporation of additive substances, especially harmless colors and flavors. The addition of substances to make a confection is, therefore, a legitimate means of manufacture. Wiley, *Foods and Their Adulteration*, 483 (1907).

"As further stated by Wiley, supra, confectionery is not a natural product, and the incorporation of harmless additives should not per se render the confection adulterated. Of the substances which are commonly added to confectionery, e.g., flavorings, sweetenings, colorings, nuts, fruits, etc., some are nutritive and others non-nutritive. It is plain, however, that the nutritive properties of confectionery, while important, are at least not as highly prized by the public as its flavor, general palatability, and attractiveness. Wiley, supra.

"The use of artificial sugars, such as saccharin and sodium cyclamate in the manufacture of a confection may possibly give rise to questions relating to a statutory standard of identity, Section 343(g), or problems of misbranding, Section 343. But, as far as adulteration, within the meaning of Section 342(d) is concerned, we hold that the statutory phrase, 'non-nutritive substances,' means only non-nutritive substances that are harmful or inedible.

"If Section 342(d) were to be read to prohibit the addition of harmless non-nutritive substances, such as saccharin and sodium cyclamate, into confectionery, this section would conflict with Section 343(j) which permits the sale of special dietary foods, when properly labeled, including foods containing

saccharin and sodium cyclamate. Interpretations that result in such conflicts should be avoided as far as reasonably possible.

"It is, therefore, our conclusion that harmless, edible saccharin and sodium cyclamate are not non-nutritive substances within the meaning of Section 342(d) and that, therefore, claimant's motion for summary judgment on the adulteration issue should be granted.

"We turn now to libelant's second contention that these candy bars have been misbranded within the meaning of Sections 343(a) and 343(g)(1). Such sections read as follows:

'Section 343. Misbranded food—

A food shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations . . ., unless (1) it conforms to such definition and standard . . .'

"The amended libel alleges that claimant's products when introduced into and while in interstate commerce were misbranded within the meaning of 21 U.S.C. Section 343(a) in that the label statements, 'Low Calorie,' 'Good for you when you diet—Good for you when you want to keep trim,' and 'For People Who Want to Keep Trim,' are false and misleading, since the article is not low in calories and will not be effective to reduce weight or keep trim; FURTHER, that the article is misbranded within the meaning of the same section in that the label statement 'WITHOUT ALL THE FATTENING CALORIES of ordinary chocolate bars' is misleading, since the article furnishes the consumer a substantial proportion of the fattening calories of ordinary chocolate bars; FURTHER, that the article is misbranded within the meaning of the same section in that the label statement 'ONLY 9 CALORIES' in bold language followed by the words 'per section' in light small print is misleading, because it creates the impression that each bar furnishes fewer calories than it does in fact, which impression is not corrected by the statement in the fine print portion of the label 'Approx. Calories per bar 76.' An examination of the affidavits indicate that these claims, denied by defendant, give rise to a genuine issue of fact which should not be resolved upon a motion for summary judgment.

"Finally, the amended libel alleges that the article is misbranded within the meaning of 21 U.S.C. Section 343(g)(1), quoted supra, in that it purports to be and is represented as milk chocolate, a food for which a definition and standard of identity has been prescribed by 21 C.F.R. Section 14.7, as provided by 21 U.S.C. Section 341, and it fails to conform to such definition and standard.

"In support of this allegation, libelant has submitted the affidavit of Osborn, Senior Chemist, Food Division, Bureau of Biological and Physical Sciences, in Washington, D.C., to the effect that saccharin and sodium cyclamate are not permitted ingredients under the definition and standard of identity for milk chocolate.

"But, claimant does not allege by affidavit or otherwise that its product *is* milk chocolate, nor does the statute require it to be. The gist of the charged misbranding under this section is that the article 'purports' to be or is represented as milk chocolate.

"This question, like others previously discussed, depends largely upon a determination of what an ordinary purchaser of this type of product would believe it to be from the label and packaging statements and in this respect a question of fact is raised which may not be resolved upon a motion for summary judgment.

"We cannot, as a matter of law, state whether this product 'purports' to be milk chocolate, and believe that, in the absence of evidence on this point, libelant's motion for summary judgment on this issue should be denied.

"We conclude that plaintiff's motion for summary judgment should be denied and that defendant's motion for partial summary judgment should be granted.

"Defendant, as prevailing party herein, will prepare an order in accordance with this opinion and in conformity with the Rules of this Court."

Thereafter the claimant moved to have the case removed to the Eastern District of New York for trial. On 5-2-61, the Government moved for a rehearing of the court's ruling which granted the claimant's motion for partial summary judgment and denied the Government's motion for summary judgment on the adulteration charge. On 5-25-61, both the motion for rehearing and the motion for removal were heard. On 7-6-61, the court rendered the following opinion denying both motions:

SWEIGERT, *District Judge:* "On April 24, 1961, this Court issued its order denying libelant's motion for summary judgment on the issues of adulteration and misbranding, and granting claimant's motion for partial summary judgment on the single issue of adulteration.

"The order was filed pursuant to our memorandum opinion of April 4, 1961, wherein we concluded that the statutory phrase, 'non-nutritive substance,' contained in 21 U.S.C. Section 342(d), means only a non-nutritive substance which is harmful or inedible, and that the statute was not intended to ban the use of such harmless, non-nutritive substances as saccharin and sodium cyclamate.

"In granting libelant's motion for a rehearing, the Court has considered further oral argument and further briefs.

"Upon re-hearing, libelant argues, among other points, that our previous ruling would adversely affect the administration of the Food, Drug and Cosmetic Act, because the government would be powerless to eliminate from confectionery those substances, called economic adulterants, which, although harmless non-nutritives, are deceptively used as cheap fillers to increase bulk and weight at the expense of quality.

"In the course of our reconsideration of our previous construction of Sec. 342(d), U.S.C. Title 18, we have examined two cases dealing with its predecessor Section, Sec. 7 of the 1906 Act, which read as follows:

> 'That for the purposes of this act an article shall be deemed to be adulterated . . .
>
> In the case of confectionery:
>
> If it contains terra alba, barytes, talc, chrome yellow, or other mineral substance or poisonous color or flavor, or other ingredient "deleterious or detrimental to health, or any vinous, malt or spirituous liquor or compound or narcotic drug." '

"In *French Silver Dragee Co.* v. *United States*, 179 F. 824 (2d Cir. 1910), involving a review of a conviction under that section for interstate shipment of silver-coated confectionery, the Second Circuit noted the purpose of the pure food act as two-fold: (1) To protect purchasers of food from being deceived by having inferior and different articles passed off upon him in place of those which he desired to obtain, and (2) To protect him from injury by prohibiting the addition to foods of foreign substances poisonous or deleterious to health. (at 825).

"In construing the section, the Court noted that the enumerated substances, terra alba, barytes and talc, although harmful, were well known economic adulterants. Chrome yellow, the Court noted, was a poisonous coloring.

"The issue before the Court was whether the lower Court had correctly interpreted the statutory phrase 'or other mineral substance' as including all mineral substances whatsoever, e.g., salt, sulphur, and baking soda, commonly used in the manufacture of confectionery, and silver, a harmless non-nutritive substance, used, not like an economic adulterant, to deceive, but merely to attract attention.

"The Court said:

'But the product in which the salt, sulphur, baking soda, or silver was used would not be unhealthful, nor would there be any element of deceit present. The provision so construed would arbitrarily prohibit the use of all mineral substances in confectionery, would accomplish thereby none of the purposes of the Act, and would apply a different standard in the case of confectionery than in the case of food or drugs. Unless the language of the statute imperatively requires such construction, it should not be adopted by the Courts.' (at 827).

"In *United States* v. *B. C. Boeckel*, 221 F. 885 (1st Cir. 1915), the Court, interpreting the same section, in a case involving the presence of talc, held that the specifically enumerated substances—terra alba, barytes, talc and

chrome yellow, and vinous, malt and spirituous liquors, rendered confectionery adulterated.

"It should be noted, however, that in reaching its conclusion the Court observed that Congress, knowing that the first three substances, although harmless, were commonly used as adulterants in confectionery to increase its weight and cheapen its quality, and that chrome yellow is an active poison, and that vinous, malt and spirituous liquors lead to pauperism and crime, saw fit to ban all of these named substances from confectionery, regardless of whether the quantity contained in any particular confectionery was such as to produce those results.

"It was because of the nature of the named substances, and their tendency to either deceive or to injure, that the Court recognized the intent of Congress to ban the enumerated substances entirely from confections and upheld that Congressional intent as reasonably related to the purposes of the Food and Drug Act.

"With respect to such unspecified substances as might fall within the general phrase 'other mineral substances,' the Court cited with approval the earlier *Silver Dragee* case for its holding that the government must establish that any such mineral is either calculated to deceive or to injure the public.

"With these interpretations of the predecessor section in mind, we do not believe that, when Congress amended the law by omitting reference to specific substances and by substituting the general phrase 'non-nutritive substances' (except 'authorized coloring, harmless flavoring, etc.'), it intended to so change and broaden the act as to prohibit for the first time substances which are neither harmful nor in the category of deceptive economic adulterants.

"The question is important to this case because the substances here involved, saccharin and sodium cyclamate, are admittedly harmless, and so far as the record herein is concerned, there is nothing to indicate that they are the kind of substances which are or could be commonly used for the purposes of economic deceit—any more than the non-nutritive, decorative silver, involved in the *French Silver Dragee* case could be so used. Indeed, the government's only contention is that they are 'harmless sweetenings' which, defendant contends, are essentially the same as 'harmless flavorings' expressly excepted even by Sec. 342(d) itself.

"Reference to the dictionary to discover the distinction, if any, between 'flavorings' and 'sweetenings' leads the Court to believe that a sweet or sweetening ('agreeable to the sense of taste; having a *flavor* like sugar; especially containing or due to sugar in some form', Funk & Wagnalls New College Standard Dictionary), is also and necessarily a flavor or flavoring ('a substance, as an essence or extract, for giving a flavor to anything', a flavor being 'the quality of anything as affecting the senses of taste or smell; the characteristic taste of a thing, especially if pleasant.'—Id.)

"Although we are of the view that a sweetening is also and necessarily a flavoring, i.e., a sweetish, sugarish flavoring, we have not rested our ruling on that ground for the reason that the government has placed in the file an affidavit of one Dr. Osborn to the effect that when a natural or artificial sweetener is added to food, the food is spoken of as sweetened to taste, not as flavored to taste.

"Nevertheless, saccharin and sodium cyclamate, whether sweetenings, flavorings or both, are, so far as this record is concerned, neither harmful nor deceptive to the public. The Court is of the opinion that, either the Congress did not intend to proscribe them from confectionery when it used the general phrase 'non-nutritive substances' or that the Congress believed and intended, as this Court believes, that such harmless sweetenings would be exempted by the exceptions of 'harmless flavorings.'

"We have examined the legislative history leading to the 1938 amendment of Sec. 7 of the 1906 Act and the recasting of it to the form of present Sec. 342(d) of Title 21.

"That history indicates that the primary purpose of the change was to get at the practice of embedding non-nutritive articles or substances, like trinkets which, although potentially harmful and inedible, would not clearly fall within the provisions of Sec. 342(a)(1), dealing with substances injurious to health, or within Sec. 342(b), dealing with substances usable as so-called economic adulterants. See, Senate Report on S. 2800, Dunn, *Federal Food, Drug and Cosmetic Act*, 114 (1938); Senate Report on S. 5, Dunn, supra, 243; House Re-

port on S. 5, Dunn, supra, at 552; Amended Report in the Senate on S. 5, Dunn, supra, at 691.

"The then head of the Food and Drug Administration, W. G. Campbell, specifically testified in the Senate hearings on the proposed legislation that the use of the phrase 'non-nutritive substance' was to take care of candy-carrying trinkets. See, Dunn, supra, at 1075.

"Libelant contends that, because Section 342(d) expressly excepts 'authorized coloring, harmless flavoring, harmless resinous glaze . . . natural gum and pectin'—that *all* other non-nutritive substances, although neither harmful, inedible nor economically deceptive, are encompassed within the ban of Sec. 342(d) on 'non-nutritive substances.'

"Apart from our view that Congress may well have believed and intended that such harmless substances as saccharin and sodium cyclamate would be exempted by the exception of 'harmless flavorings,' we do not in any event believe that Congress intended to ban their use under the general phrase 'non-nutritive' substance or ban the use of any substance in confectionery, which, tending neither to public injury or deceit, would not be reasonably related to the purposes of the Act.

"It is, therefore, our opinion that the present section carries forward the ban of the previous section on substances injurious to health (like poisonous chrome yellow), as well as the earlier section's ban on deceptively used economic adulterants (like terra alba, barytes and talc). Further, as already noted, the present section was intended to go further to plug up 'one of the serious loopholes of the old law,'—its failure to reach the practice of using in confectionery such harmful articles as metallic trinkets. See, House Report on S. 5, Dunn, supra, at 552, 691, 1065.

"A further consideration supports our interpretation of the section.

"Libelant concedes that under Section 343(j), the special provision dealing with foods for special dietary uses, products which contain saccharin and sodium cyclamate, may be legally introduced for interstate shipment if they are for special dietary uses and if they comply with the particular regulations required by that section with respect to labeling. (See, Libelant's Brief, 11–9–60, p. 20.)

"There is no contention that the product here involved is not for special dietary use or that it does not comply with those regulations.

"Libelant's position on this point is that its further regulation issued under Section 343(j) provides that such regulations should not be construed as exempting any food from any other provision of the Act. (Libelant's Brief, 11–9–60, p. 20.)

"The practical effect of the last mentioned regulation, in which the agency assumes to construe the statute, is that a special dietary use product containing saccharin and/or sodium cyclamate, and complying with the labeling provisions of Section 343(j), may be legally introduced into interstate commerce, *unless it happens to be also a confection.* In this latter case, according to the government's interpretation of Section 342(d), it cannot be introduced, even though it is harmless, not a deceptive economic adulterant, and is properly labelled under Section 343(j).

"Such an anomalous, harsh and inexplicable result should be avoided if possible. It is avoided, and effect given to all pertinent sections of the Act, by our construction of Section 342(d).

"Under this construction, the government will be under no greater difficulty in Section 342(d) cases, involving the general phrase 'non-nutritive substance,' than it was in cases under the former section, involving the phrase 'other mineral substances,' wherein the government was obliged to show that the substance was either harmful or usable as an economic adulterant. (See, *French Silver Dragee*, supra.)

"In anticipating a refusal to reconsider our former ruling, which was of the type from which an interlocutory appeal would not ordinarily lie, (6 *Moore's Federal Practice*, Par. 56.20[4] p. 2311,) libelant has requested this Court to certify the case as appropriate for an interlocutory appeal under the provisions of 28 U.S.C. Section 1292(b).

"Under that section it is necessary for this Court to include in its opinion certain recitals to the effect that the Court is of the opinion that its order 'involves a controlling question of law as to which there is substantial ground

for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation.'

"The section was intended primarily as a means of 'expediting litigation by permitting appellate consideration during the early stage of litigation of legal questions which, if decided in favor of the appellants would end the lawsuit.' *United States* v. *Woodberry*, 263 F. 2d 784, 787 (9th Cir. 1959).

"This lawsuit would not be ended even if summary judgment were entered in favor of libelant on the issue of adulteration. There still remains the issue of misbranding which involves questions of fact to be tried. The adulteration issue does not present a controlling question of law because both issues are separate and independent of each other. For these reasons, the Court is unable to certify this matter to the appellate court under Section 1292(b).

"There remains claimant's motion to remove to the Eastern District of New York, made pursuant to the provisions of 21 U.S.C. Section 334(a).

"Since a seizure action is a statutory in rem proceeding, the jurisdiction of this Court is based upon the presence of the goods within the district. Accordingly, the general removal provisions of 28 U.S.C. Section 1404 (a) and (b), permitting transfer to any district in which the action could have been brought originally and permitting transfer between divisions of the same district, is inapplicable because seizure actions must be brought where the goods may be found. See: *United States* v. *23 Gross Jars of Enca Cream*, 86 F. Supp. 824 (N.D. Ohio 1949).

"Section 334(a) of Title 21, provides for a change of venue in seizure actions under the Food and Drug Act. In certain cases transfer is allowed upon petition of the claimant to a district agreed upon by stipulation between the parties, and, failing this, unless good cause otherwise appears, to a district of reasonable proximity to claimant's principal place of business.

"This privilege is, however, restricted in single seizure actions, such as the present, to misbranding cases. *United States* v. *74 Cases . . . C. C. Brand Oysters*, 55 F. Supp. 745 (W.D.S.C. 1944). Removal is not provided by statute for single adulteration libels, and it has been held that transfer may not be authorized where, as here, the single libel charges both adulteration and misbranding. *United States* v. *11 Cases of Ido-Phon-Chon*, 94 F. Supp. 925 (D. Oreg. 1950), 2 Kleinfeld & Dunn, *Federal Food, Drug and Cosmetic Act*, 178 (1949–50); see, also, *Clinton Foods, Inc.* v. *United States*, 188 F. 2d 289 (4th Cir. 1951).

"Claimant has taken the position that this Court's order, granting partial summary judgment in claimant's favor on the issue of adulteration removes that issue from the case and that the libel should be considered at this juncture as though the adulteration issue had never been pleaded. (Claimant's Reply Brief, 2.)

"We cannot agree. The issue of adulteration, though the subject of an interlocutory summary adjudication, has not been removed from the case. It remains part of libelant's case and will be reviewable on appeal from final judgment.

"In response to claimant's suggestion that the government, as libelant in this action, could effectively read Section 334(a) entirely out of the statute by pleading an adulteration charge in each case, even though frivolous or insufficient in law, we may state that libelant's charge of adulteration in this case is bona fide and not plainly without merit.

"It is, therefore, the opinion of the Court that claimant's motion to remove to the Eastern District of New York should be denied.

"Another matter yet remains. In our former memorandum opinion, we noted that libelant had failed in its libel to negate the possibility that saccharin and sodium cyclamate, although non-nutritive, are harmless flavorings within the meaning of the statutory exception relating such substances. We expressed the view that, unless such exception is negated, the libel, for that reason, fails to state a case of adulteration under the section.

"Upon the authorities, however, (*McKelvey* v. *United States*, 260 U.S. 353 (1922); *United States* v. *Safeway Stores, Inc.*, 252 F. 2d 99, 101 (9th Cir. 1958); and *Bowles* v. *Wheeler*, 152 F. 2d 34, 41 (9th Cir. 1945), cert. den. 326, S. 775 (1945), we now conclude that the libel need not negate the exception relating to harmless flavorings.

"Claimants will prepare an order in accordance with this memorandum opinion and in conformity with the rules of this Court, denying libelant's motion to reconsider.

"Libelant will prepare an order in accordance with this memorandum opinion and in conformity with the Rules of this Court, denying claimant's motion to remove."

On 7–12–61, the court rendered a supplemental memorandum opinion which indicated the court's willingness to certify for the purpose of an interlocutory appeal under section 1292(b) of Title 28, United States Code, that its ruling on the adulteration issue involved a controlling question of law as to which there was substantial ground for difference of opinion. However, on 12–8–61, in view of the strong policy against piecemeal appeals, and because the remaining issue of misbranding might be tried in several days, the court set its supplemental opinion aside and ordered that the case proceed to trial forthwith.

On 3–16–62, a consent decree of condemnation and destruction was filed, claimant moving that a decree, as prayed for in the libel with respect to the misbranding charges, be entered condemning the article under seizure, and the Government without waiving its right of appealing the court's order granting partial summary judgment, offering no objection. On 3–16–62, a partial summary judgment in favor of the claimant on the adulteration charge was also filed. On the same date the district court filed a stay of the order of destruction, thereby directing the U.S. marshal not to destroy the article under seizure until the Government had exhausted all appeal rights in this case. On 5–14–62, the Government appealed the court's partial summary judgment in favor of the claimant on the adulteration charge. On 1–14–63, the United States Court of Appeals for the 9th Circuit rendered the following opinion (313 F. 2d 219):

PER CURIAM: "In this case the United States filed a libel against the above-mentioned Candy Bars alleging that the candy bars were (a) adulterated and (b) misbranded in violation of the Federal Food, Drug, and Cosmetic Act. Following proceedings in the court below, the court adjudged that the candy bars were not adulterated within the meaning of the applicable statute but adjudged that the same were misbranded and ordered them condemned and destroyed for this reason. United States has appealed from that portion of the judgment of the court below which found the candy bars not adulterated. No other appeal has been taken and the decree of condemnation ordering destruction of the candy bars because misbranded has become final. Appellee asserts that appellant's appeal is moot and should be dismissed.

"We are of the opinion that under the circumstances stated the matter determined against the United States is immaterial or moot, and that the motion to dismiss the Government's appeal should be granted.

"IT IS THEREFORE ORDERED AND ADJUDGED that the appeal of the United States be, and the same is hereby dismissed as moot. So much of the judgment below as dealt with the issue of adulteration is vacated and set aside, and the same is and shall be without further force and effect. *Duke Power Company* v. *Greenwood County*, 299 U.S. 259, 267, and cases cited in *United States* v. *Munsingwear*, 340 U.S. 36, 39, footnote 2. See also *Benz* v. *Compania Naviera Hidalgo S.A.*, 9 cir., 205 F. 2d 944, 947."

28994. **Bio-C-Complex tablets.** (F.D.C. No. 48328. S. No. 34–101 V.)

QUANTITY: 240 100-tablet btls., at Minneapolis, Minn.

SHIPPED: 5–16–61, from Worcester, Mass., by Brewer & Co., Inc.

LABEL IN PART: (Btl.) "Cayol * * * Natural & Organic Bio-C-Complex Vitamin C . . . 100 mg. Rutin . . . 50 mg. Citrus Bioflavonoids . . . 60 mg. Distributed by Cayol Foods * * * Minneapolis, Minn. * * * Directions * * * Indications—As A Dietary Supplement."